

Applicant: Kujawski, D.
Application No.: 10/823,061
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Arguments/Remarks:

Claims 1-8, 10-34 and 36-38 are pending. Claims 22-33 are withdrawn. Claim 1 has been amended to describe the petal-like projections as having, inter alia, non-connected distal portions, and claim 34 has been amended to describe the non-tubular woven projections as having, inter alia, non-connected distal portions. Support for these amendments may be found in the specification at paragraph [0023]. Claim 10 has been amended and claim 38 has been added. Support for these claim amendments may be found in the specification art paragraph [0035]. No new matter is introduced with these amendments. Entry of the amendments is respectfully requested.

Moreover, the Advisory Action, dated December 12, 2007, stated that the proposed amendments of the Amendment And Response Pursuant To 37 C.F.R. §1.116, filed November 20, 2007, were not considered as they would allegedly raise new issues that would require further consideration and/or search. Therefore, pursuant to MPEP §706.07(b) a final rejection on the January 22, 2008 Amendment and Response is not proper. These comments are being made because the first page of the Office Action is listed as non-final, but page 5 of the Office Action appears to indicate a final office action. Further, the status of this case on the Patent Office's PAIR system lists the office action as non-final. Thus, applicant respectfully submits that the Office Action dated April 14, 2008 is a non-final office action

Section 112 Rejections

Claims 1-8, 10-21, 34, 36 and 37 were rejected under 35 U.S.C. § 112, first and second paragraphs. Applicant respectfully submits that with the amendments presented herein that the Section 112 rejections are traversed. Reconsideration and withdrawal of the Section 112 rejections are respectfully requested.

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Section 103 Rejections

Claims 1-21, 34, 36 and 37 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent Application Publication No. 2003/0139805 to Holmberg et al. (hereinafter "Holmberg") in view of U.S. Patent Application Publication No. 2003/0078650 to Nunez et al. (hereinafter "Nunez"). Applicant respectfully traverses.

Holmberg is directed to a prosthesis for aorta or pulmonary replacement. (Holmberg, paragraph 0001). The prosthesis 120 of Holmberg has a cylindrical section 122 and an expanded section 124 having three sinuses 134, 136, 138. (Holmberg, paragraph 0063; Figure 2). In another embodiment an expanded section 104 is free of sinuses. (Holmberg, Figure 1).

The prosthesis of Holmberg is formed from a sheet of material which is cut, shaped and fastened to form a tubular structure. (Holmberg, paragraph 0053). The sheet of Holmberg may be made from woven polyester. (Holmberg, paragraph 0069).

Construction of the prosthesis of Holmberg is discussed at paragraphs 0090-0102 and depicted in Figures 14-22. As depicted and described in conjunction with Figure 14, a sheet material 540 may be cut into a rectangular portion 542 and an expanded portion 544. (Holmberg, paragraph 0093). The edges of the portions 542, 544 are folded over and fastened together to form the prosthesis of Holmberg. (*Id.*) The expanded portion may be in the shape of a truncated circle as depicted by portion 544 in Figure 14 or in the shape of a rectangle as depicted by portion 564 in Figure 16. A mandrel 550 may be used to shape the flat sheets of Holmberg into a tubular shape. (Holmberg, paragraph 0094; Figure 15). Leaflet sections 604, 606, 608, 610, 612, 614 are separately cut from a sheet of material and are fastened to conduit portions 602, 616. (Holmberg, paragraph 0102; Figures 21 and 22).

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Thus, Holmberg fails to disclose, teach or suggest the graft of claim 1 which comprises, *inter alia*, a seamless tubular woven portion and a seamless woven portion because the edges of the cut sheet material of Holmberg must necessarily be fastened together at a seam to form its tubular structure. Further, Holmberg fails to disclose, teach or suggest, *inter alia*, a contiguously woven bulbous section having a greater number of warp yarns than fill yarns, as set forth in independent claim 1. Moreover, Holmberg fails to disclose, teach or suggest, *inter alia*, a plurality of petal-like projections seamlessly woven from an end of the bulbous section, as set forth in independent claim 1.

In a similar fashion, Holmberg fails to disclose, teach or suggest a prosthesis comprising, *inter alia*, a seamless tubular woven portion and a plurality of non-tubular woven portions seamlessly transitioned therefrom because the edges of the cut sheet material of Holmberg must be fastened together to form its tubular device.

It is respectfully submitted that Nunez fails to cure all of the deficiencies of Holmberg. Nunez fails to teach or suggest a bulbous woven portion. Nunez does teach a seamless bifurcated or trifurcated woven graft, as depicted in Figures 15-18. Tubular iliac woven portions 630a, 630b are seamlessly woven from an aortic portion 620, as depicted in Figure 15 of Nunez. (see also, Nunez, paragraph 0075). Tubular iliac woven portions 730a, 730b, 830a, 830b, 930a, 930b, 930c are similarly seamlessly woven from aortic portions 620, 920 as depicted in Figures 16-18. Thus, Nunez fails to disclose, teach or suggest a seamlessly woven graft comprising, *inter alia*, petal-like projections that are non-tubular, contoured, lobate-shaped woven sheets having non-connected distal portions, as set forth in independent claim 1, and a prosthesis comprising, *inter alia*, non-tubular woven projections that are non-tubular, contoured, lobate-shaped woven sheets having non-connected distal portions, as set forth in independent claim 34. In particular, Nunez fails to teach or suggest a graft having, *inter alia*, a plurality of non-tubular

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woven projections seamlessly transitioned from a tubular end of a graft, in particular non-tubular woven projections that are non-connected, contoured, lobate-shaped woven sheets.

While Holmberg teaches a graft having petal-like projections, such projections of Holmberg are contrary to the teaching of Nunez because Nunez specifically teaches away from having its iliac woven portions separately formed from its aortic portion followed by fastening, for example by suturing, the separately formed tubular woven portions. (Nunez, paragraph 0069).

The examiner may not properly ignore these specific teachings of Holmberg and Nunez in presenting the section 103 rejections. In other words, Nunez teaches away from the grafts and methods of Holmberg. Further, Nunez fails to disclose, teach or suggest how contoured, non-tubular, petal-like projections may be seamlessly woven from its seamless main graft portion. Holmberg also fails to disclose, teach or suggest how contoured, non-tubular, petal-like projections may be seamlessly woven from a seamless main graft portion. Any attempt to modify the teachings of Holmberg and Nunez to read on the claims of the subject application is clearly hindsight reconstruction. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Applicants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

The Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. ____; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. For example, the following statements from *KSR* show the importance of predictability:

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The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. (82 U.S.P.Q.2d 1395).

If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. (82 U.S.P.Q.2d 1396).

A court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. (82 U.S.P.Q.2d 1396).

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. (82 U.S.P.Q.2d 1397).

In view of the *KSR* decision, the USPTO published new obviousness guidelines for examiners on October 7, 2007. (See, Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* 57526 Federal Register, Vol. 72., No. 195, October 10, 2007.) The PTO guidelines require “clear articulation of the reason(s) why the claimed invention would have been obvious” by quoting the following from the *KSR* decision:

[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. (*Id.* at 57528, column 3, to 57529, column 1).

The USPTO then identified seven different “rationales” to reject claims for obviousness based on *KSR*, *i.e.*, rationales A-G. In each, the word “predictable” or the phrase “reasonable expectation of success” appears in the heading, the text underneath the heading, or both. For example:

- A. “Combining Prior Art Elements to Known Methods to Yield Predictable Results.” (*Id.* at 57529, column 1).
- B. “Simple Substitution of One Known Element for Another to Obtain Predictable Results.” (*Id.* at 57530, column 1).

- C. Use of Known Technique to Improve Similar Devices (Methods, or Product) in the Same Way
One of ordinary skill in the art would have been capable of applying this known method of enhancement to a 'base' device (method, or product) in the prior art and the results would have been predictable. (*Id.* at 57530, column 3).
- D. "Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement to Yield Predictable Results" (*Id.* at 57531, column 1).
- E. "Obvious to Try" – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success" (*Id.* at 57532, column 1).
- F. Known Work in One Field of Endeavor May Prompt Variations of it for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if The Variations Would Have Been Predictable to One of Ordinary Skill in the Art"
The rationale to support a conclusion that the claimed invention would have been obvious is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention. (*Id.* at 57533, column 1).
- G. Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill to Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention
(2) a finding that there was reasonable expectation of success". (*Id.* at 57534, column 1).

Accordingly, a proper rejection of a claimed method based on obviousness requires the examiner to explain how the prior art leads a person skilled in the art reasonably to predict or expect that the claimed invention will be successful.

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Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd., 83 USPQ2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness. Again, predictability of success is required.

Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. (*Id.* at 1176).

...the court found that there was no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes. (*Id.* at 1177).

...we disagree with Alphapharm that that statement provided a reasonable expectation to one of ordinary skill in the art that performing the specific steps of replacing the methyl group of the 6-methyl compound with an ethyl group, and moving that substituent to the 5-position of the ring, would have provided a broad safety margin ... (*Id.* at 1178-1179).

Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."

Clearly, the disclosures of Holmberg and Nunez do not provide sufficient predictability or expectation to support a *prima facie* case of obviousness. Nunez fails to teach or suggest a seamlessly woven graft having non-tubular woven projections seamlessly transitioned from a main seamlessly woven graft portion. Holmberg fails to teach or suggest that its graft having non-tubular woven projections may be a seamlessly woven graft. Nunez fails to teach or suggest a bulbous woven portion. Holmberg fails to teach or suggest a seamlessly woven bulbous portion. The expectation and predictability to arrive at the present invention though Holmberg and Nunez do not rise to a level that represents a *prima facie* case of obviousness.

Thus, it is respectfully submitted that Holmberg and Nunez, individually or in combination, fail to teach or suggest the invention as presently defined by independent claims 1

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and 34. Reconsideration and withdrawal of the rejection of claims 1 and 34, and all claims dependent therefrom, are respectfully requested.

Summary

Therefore, Applicants respectfully submit that independent claims 1 and 34, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

/John S. SOPKO, Reg.# 41321/
John S. Sopko
Registration No.: 41,321
Attorney for Applicant

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700